

## REMARKS

Claims 1-7 and 10-35 are pending in this application. Reconsideration of the claims in view of the following remarks is respectfully requested.

### 35 U.S.C. § 103 Rejections

Claim 1 recites, *inter alia*, (1) “hollow lancet having a tip adapted to puncture skin and to collect a body fluid sample, the interior of the hollow lancet forming a channel for moving a fluid sample from the tip to a reaction area” and (2) “an inner end cap disposed within the outer end cap, the inner end cap having a first end coupled to the open end of the body and a second end forming a second aperture therein that the tip of the lancet enters when in the lancing position, the second end being adapted to contact the skin of the test subject when the lancet is in the collecting position, the inner end cap having a wall extending to the second end thereof, the wall of the outer end cap extending farther towards the skin than the wall of the inner end cap during lancing such that the skin of the test subject is drawn inside of the outer end cap and contacts the inner end cap.”

The claimed inner and outer end caps are advantageous as explained in the present invention because the outer end cap contacts a test subject’s skin and the test subject’s skin is pulled against the inner end cap during the lancing operation. See page 3, lines 23-29 of the patent application. Thus, the test subject’s skin is stretched flat against the open end of the inner end cap and “[t]his stretched, flat skin facilitates sample formation and collection.” See page 6, lines 20-22 of the patent application.

The Office Action has applied two references to claim 1-- U.S. Patent No. 5,951,492 to Douglas (“Douglas”) and U.S. Application Publication No. 2003/0171696 to Dosmann (“Dosmann”). As recognized in the Office Action, Douglas does not disclose “a hollow lancet having a tip adapted to puncture skin and to collect a body fluid sample, the interior of the hollow lancet forming a channel for moving a fluid sample from the tip to a reaction area” as recited in claim 1. See page 3 of the Office Action. Additionally, as will be discussed below, the Applicants believe that Douglas also does not disclose, teach or suggest the claimed inner end cap.

In an attempt to address the hollow lancet deficiency in Douglas, the Office Action has applied Dosmann. See page 3-4 of the Office Action. Specifically, the Office Action applies

Dosmann and states that “it would have been obvious to one of ordinary skill at the time of[] the invention to substitute Douglas’ disposable element comprising separate needle and capillary tube connected to a test element with Dosmann’s singular hollow lancet for lancing the skin and collecting fluid through the interior of the lancet in order to improve test time by integrating the lance, harvest and analysis operation as taught by Dosmann. Page 4 of the Office Action. The Applicants respectfully disagree.

#### Douglas Does Not Disclose the Claimed Inner End Cap

Douglas does not disclose, teach or suggest the claimed inner end cap of claim 1. Specifically, Douglas does not have an inner end cap “having a second end forming a second aperture therein that the tip of the lancet enters when in the lancing position, the second end being adapted to contact the skin of the test subject when the lancet is in the collecting position, the inner end cap having a wall extending to the second end thereof, the wall of the outer end cap extending farther towards the skin than the wall of the inner end cap during lancing such that the skin of the test subject is drawn inside of the outer end cap and contacts the inner end cap” as recited in claim 1.

The Office Action improperly equates an inner sleeve 66 in Douglas as disclosing the claimed inner end cap and further states that the skin contacts the inner sleeve 66 and cites to FIGs. 5 and 6 of Douglas. Page 3 of the Office Action. The differences between Douglas and the present invention may be shown by comparing FIG. 6 of Douglas and FIGs. 3 and 4 of the present invention.

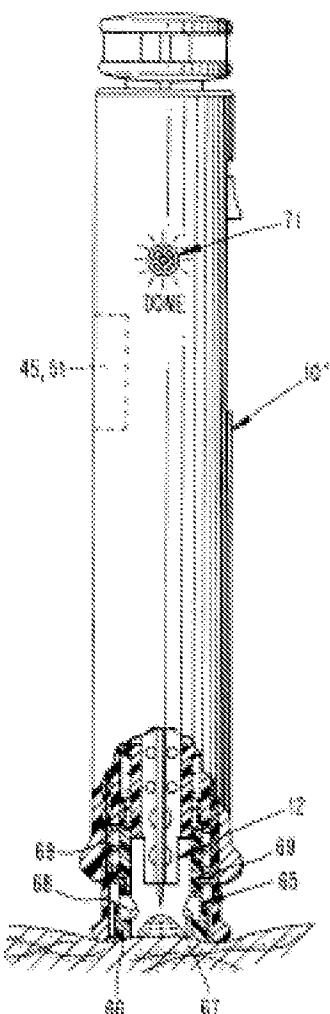


FIG. 6

Fig. 3

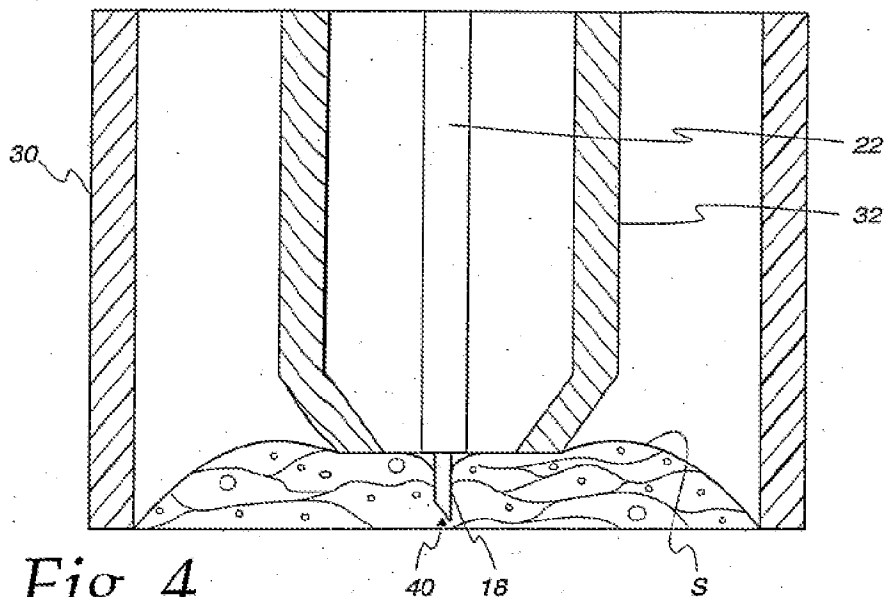
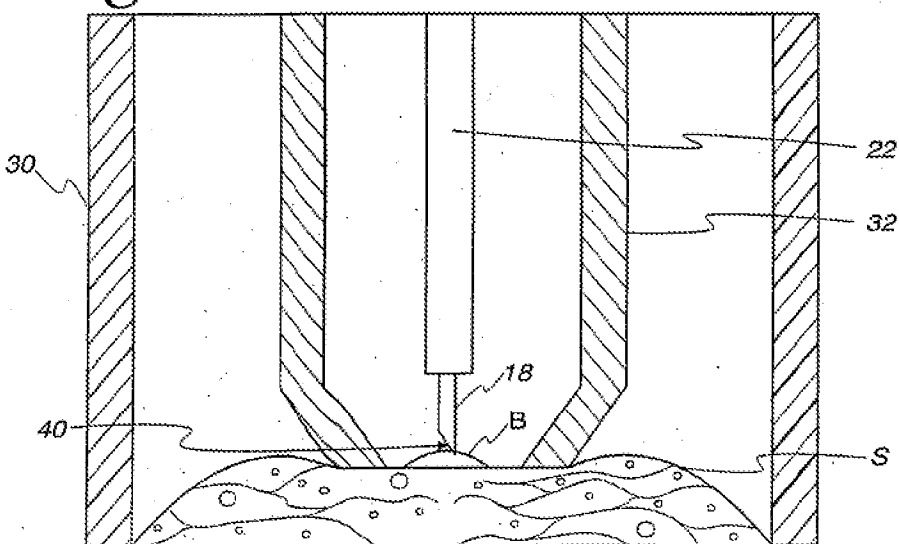


Fig. 4



More specifically, FIG. 6 of Douglas discloses a drop sensing mechanism 65 whose function is to determine whether a drop of body fluid is of a sufficient size. Col. 7, lines 29-45 of Douglas. The drop sensing mechanism 65 is mounted in an inner sleeve 66 and includes elements 67 and 68 that in one embodiment are electrodes. *Id.* The electrodes make contact with the drop of body fluid only if the drop is of a sufficient height. *Id.* The elements 67, 68 of Douglas in another embodiment are a light emitter or light receiver. See col. 7, lines 46-52. Douglas discloses that element 67, which is located opposite of sleeve 66 in FIG. 6, makes

contact with the fluid – there is no mention of contact with the skin. FIG. 6 of Douglass appears to show the sleeve 66 contacting the skin, but there is no written discussion of this and certainly no disclosure of (1) the second end of the inner end cap contacting the skin when the lancet is in the collection position and (2) the wall of the outer end cap extending farther towards the skin than the wall of the inner end cap during lancing such that the skin of the test subject is drawn inside of the outer end cap and contacts the inner end cap as recited in claim 1.

There is No Teaching or Suggestion to a Skilled Person to Combine Douglas and Dosmann for Several Reasons

First, the lancing mechanism of Douglas is quite different from that of Dosmann. The lance of Dosmann is unmovable and, thus, has a single position. See par. 10, lines 4-5 of Dosmann; FIG. 1. The housing 18 of Dosmann controls the depth of a puncture into a patient's skin by the lance 12. Par. 10, lines 4-5. The depth of a puncture corresponds to the length of the lance 12 extending out of the housing 18. Dosmann; Par. 10, 5-7. Douglas, on the other hand, is movable and is adapted to move between retracted and lancing positions. See, e.g., FIGs. 1, 2, 5 and 6.

Second, Dosmann discloses that it is a disposable optical format/integrated lance for lancing the skin. See abstract of Dosmann. Douglas does not disclose a disposable lancing device, but rather only discloses a disposable lancet 12. See col. 6, lines 57-63 of Douglas. The lancing device disclosed in Douglas is reusable after the disposable lancet 12, capillary tube 18 and test strip 30 are discarded. Thus, the devices disclosed in Dosmann and Douglas have different uses – the lance of Dosmann is disposable, while the lancing device of Douglas is reusable.

Thus, in summary, a skilled person would not look to combine the disposable unretracted integrated lance with optical format of Dosmann with the relatively complex lancing mechanism of Douglas.

Therefore, claim 1 is not obvious over Douglas, Dosmann or the combination thereof for at least these reasons. Thus, claim 1 should be in a condition for allowance.

#### Dependent Claims 2-7, 10, 11 and 35

For at least the same reasons as discussed above with respect to independent claim 1, dependent claims 2-7, 10, 11 and 35 also are not obvious over Douglas, Dosmann or the combination thereof.

#### Independent Claim 12

Claim 12 recites, *inter alia*, (1) “positioning the punctured skin against an edge of an inner end cap of the device, the inner end cap being disposed within the outer end cap”; (2) “disposing the tip of the lancet a predetermined distance from the skin pulled against the edge of the inner end cap;” and (3) “collecting the body fluid sample from the puncture skin with the tip of the lancet in a collection position.” Claim 12 also recites the lancing and collection device including a hollow lancet having a tip for puncturing skin. For the same reasons as discussed above in claim 1, Douglas, Dosmann or the combination do not teach or suggest the above features of claim 12. Specifically, Douglas does not disclose, teach or suggest puncturing the skin against an edge of an inner end cap and then disposing the tip of the lance with the skin pulled against the edge of the inner end cap, and collecting the body fluid sample with a hollow lancet in a collection position. Additionally, there is no teaching or suggestion to a skilled person to combine Douglas and Dosmann for the reasons discussed above in claim 12.

Therefore, claim 12 is not obvious over Douglas, Dosmann or the combination thereof and, thus, claim 12 should be allowable.

#### Dependent Claims 13-19

For at least the same reasons as discussed above with respect to independent claim 12, dependents claims 13-19 also are not obvious over Douglas, Dosmann or the combination thereof. Therefore, claims 13-19 should also be in a condition for allowance.

#### Independent Claim 20

Claim 20 recites, *inter alia*, (1) “lancing the skin of a test subject with the hollow lancet by moving from the retracted position to a lancing position, an interior of the hollow lancet forming a capillary channel”; (2) “collecting a body fluid sample from the lanced skin in the capillary channel of the hollow lancet in the collection position”; and (3) “analyzing the body

fluid sample for determining the analyte concentration in the body fluid sample while the collected body fluid sample remains in the lancet. As recognized in the Office Action, Douglas does not disclose, *inter alia*, a hollow lancet having a tip adapted to puncture skin and to collect a body fluid sample, the interior of the hollow lancet forming a channel in which collecting a body fluid sample as recited in claim 20. See page 3 of the Office Action. As discussed above with respect to claim 1, there is no teaching or suggestion to a skilled person to combine Douglas and Dosmann. Therefore, claim 20 is not obvious over Douglas, Dosmann or the combination thereof and, thus, claim 20 should be allowable.

#### Dependent Claims 21-34

For at least the same reasons as discussed above with respect to independent claim 20, dependents claims 21-34 also are not obvious over Douglas, Dosmann or the combination thereof. Therefore, claims 21-34 should also be in a condition for allowance.

### CONCLUSION

The Applicants submit that the claims are in a condition for allowance and action toward that end is earnestly solicited. The Commissioner is authorized to deduct the \$130.00 fee for a one-month extension of time. Should any additional fees be required (except for payment of the issue fee), the Commissioner is authorized to deduct the fees from Nixon Peabody LLP Deposit Account No. 50-4181, Order No. 247082-000090USPX.

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